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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,308	04/22/2005	Hideaki Kito	029650-168	1506

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EXAMINER

MEHTA, BHISMA

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,308	<b>Applicant(s)</b> KITO ET AL.	
	<b>Examiner</b> Bhisma Mehta	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/22/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities: Reference character 228b is used for grooves in line 3 of page 36 and for ribs in line 4 of page 36.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Utterberg (U.S. Patent No. 5,047,021). Utterberg discloses a syringe comprising a mouth portion at the distal end of an outer hollow cylinder (300) with a male taper portion (310) to be fitted in a bore portion of a first female connector and a bore portion of a second female connector and a passage. In lines 48-51 of column 5), Utterberg discloses that the male taper portion may puncture or be fitted in a bore portion of a first female connector (200). The syringe also comprises a lock adapter (320) that is provided at an outer peripheral portion of the mouth portion. The lock adapter is relatively movable in the axial direction of the mouth portion and relatively rotatable about the mouth portion. The lock adapter has a male-side screw engagement portion

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(326) for making screw engagement with a female-side screw engagement portion (15).

The lock adapter can be retracted to a retraction position as shown in Figure 7 where the male taper portion may be fitted into the bore of a first female connector (see line 64 of column 6 to line 13 of column 7). In Figure 6, Utterberg shows a distal end fixation position where the lock adapter is fixed to the mouth portion. In lines 32-49 of column 6, Utterberg teaches that the lock adapter is relatively rotatable about the mouth portion on the distal end side relative to the retraction position. As to claim 6, the male taper portion protrudes beyond the distal end of the lock adapter by not less than 2.1 mm as shown in Figure 6 and disclosed in lines 26-31 of column 6. As to claim 7, the lock adapter is considered to be relatively movable by not less than 5.4 mm along the axial direction of the mouth portion as it is capable of being moved along the entire length of the mouth portion. As to claim 8, the inside diameter of the mouth portion is seen to be not less than 1.2 mm as the inside diameter varies along the length of the mouth portion and the male taper portion can be fitted into the bore of the first female connector with an inner diameter of about 5.1 mm.

4. Claims 1, 2, 4, 5, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Gettig et al (U.S. Patent No. 5,609,584). In Figure 11, Gettig et al show a cap (240) to be mounted to a mouth portion of a syringe outer hollow cylinder (112) having a male taper portion (136) and a lock adapter (200) provided at an outer peripheral portion of the mouth portion. The lock adapter is relatively movable and relatively rotatable along the axial direction of the mouth portion and has a male-side screw engagement portion (222) for making screw engagement with a female-side

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screw engagement portion of a connector. The lock adapter can be retracted to a retraction position as shown in Figure 11A where the male taper portion may be fitted into the bore of a female connector. In line 59 of column 6 to line 20 of column 7, Gettig et al disclose a distal end side fixation position where the lock adapter is initially fixed onto the distal end of the mouth portion and a rotation permitting position where the lock adapter is relatively rotatable about the mouth portion on a distal end side relative to the retraction position. The cap (240) has a bottomed hollow-cylindrical cap main body with a bore portion (shown at 208 in Figure 11), a female-side screw engagement portion for screw engagement with the male-side screw engagement portion (222), and a packing formed of an elastic material provided in the bore portion of the cap main body where at least a part of the inner peripheral surface of the bore portion makes close contact with the male taper portion over the entire circumference when the cap main body is mounted to the mouth portion. In line 64 of column 7 to line 8 of column 8, Gettig et al disclose that the cap creates a fluid-tight seal to maintain the sterility of the mouth portion. As to claim 13, Gettig et al disclose the syringe having a syringe outer hollow cylinder, a lock adapter, a cap, and a liquid preparation filling the syringe outer hollow cylinder and further teach sterilizing the syringe outer hollow cylinder and cap (see lines 49-61 of column 5), mounting the cap to the mouth portion, and feeding the liquid preparation into the syringe outer hollow cylinder (see lines 58-63 of column 3). Gettig et al teach maintaining sterility which is accomplished by using the syringe in a sterile environment.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Utterberg (U.S. Patent No. 5,047,021). Utterberg discloses a syringe where the male taper portion protrudes beyond the distal end of the lock adapter by at least about 4 mm when the lock adapter is in a retraction position as shown in Figure 7. In lines 38-58 of column 4, Utterberg discloses that the length of the male taper portion which protrudes beyond the lock adapter is chosen such that the syringe is capable of piercing commonly used female connectors such as the fluid bag ports which is shown in Figure 3. In lines 24-42 of column 3, Utterberg teaches that the distance between a membrane to be punctured or spiked and the opening of the fluid bag port is about 9.0 mm. Therefore, it is seen that the desired length of the male taper portion which protrudes beyond the lock adapter would be chosen depending on the type and length of the female connector to which it is to be connected and thus this length could be chosen to be no less than 7.5 mm. Similarly, the length of the mouth portion could be chosen to be in the range of 16 to 20 mm depending on the type and length of the female connector to which it is to be connected.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Utterberg (U.S. Patent No. 5,047,021) in view of Langer et al (U.S. Patent No.

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6,004,295). Utterberg discloses the syringe substantially as claimed. However, Utterberg is silent on a gasket being slidable in the outer hollow cylinder and a volume of space defined by the outer hollow cylinder and the gasket being not more than 0.1 mL when the gasket is located at the distal end of the outer hollow cylinder. Langer et al disclose a syringe having an outer hollow cylinder (32) and a gasket (38) where the volume of space defined by the outer hollow cylinder and the gasket is not more than 0.1 mL when the gasket is located at the distal end of the outer hollow cylinder as the syringe is capable of delivering aliquots of fluid over a volumetric range of 0.05-1 mL where the volume delivered can correspond to the entire internal volume in the outer hollow cylinder. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the syringe of Utterberg with a gasket slidable in the outer hollow cylinder where a volume of space defined by the outer hollow cylinder and the gasket is not more than 0.1 mL when the gasket is located at the distal end of the outer hollow cylinder as taught by Langer et al as Langer et al teach that it is desirable to use a gasket to transfer medication from a syringe and to further provide for the delivery of specific volumes of medications such as between 0.05 and 1 mL.

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gettig et al (U.S. Patent No. 5,609,584) in view of Tucker et al (U.S. Patent No. 6,632,199).

Gettig et al disclose the method substantially as claimed. However, Gettig et al are silent on mounting the cap to the mouth portion and performing sterilization under this condition. In lines 1-9 of column 4, Tucker et al teach mounting a cap onto a mouth portion of a syringe and then performing sterilization. It would have been obvious to

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one having ordinary skill in the art at the time the invention was made to mount the cap onto the mouth portion of the syringe of Gettig et al and then sterilize the cap and the syringe as taught by Tucker et al as both Gettig et al and Tucker et al teach providing a syringe with a cap for the purpose of maintaining a sterile condition and Tucker et al teach that it is well known to perform sterilization after a cap has been mounted to a syringe.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cross (U.S. Patent No. 4,266,815), Ruschke (U.S. Patent No. 4,452,473), DeCaprio et al (U.S. Patent No. 5,184,742), Johnson (U.S. Patent No. 5,702,374), Battiato et al (U.S. Patent No. 5,855,568), and Imbert (U.S. Patent No. 6,027,482) teach syringes with lock adapters for connection with other medical devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
BM

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

